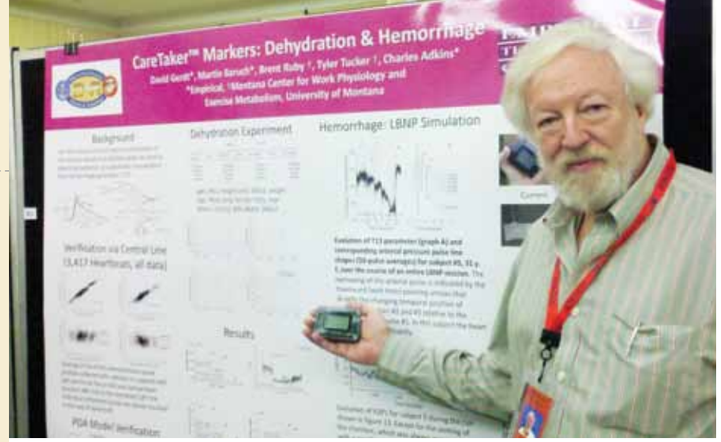
EMPIRICAL TECHNOLOGIES CORPORATION

David Gerdt,
Chief Executive Officer

The primary mission of Empirical Technologies Corporation is the development of sensor technologies that monitor the physiological behavior of humans and animals. The company has been heavily involved in combat-casualty care for the Office of Naval Research, and in 2009, Empirical won over one million dollars in funding to develop a combat-casualty care monitor that would measure a person's heart rate, beat-by-beat continuous blood pressure, respiration rate, hemorrhaging, and dehydration.

This monitor would eventually be known as CareTaker, and as Chief Executive Officer David Gerdt explained, it would become the cornerstone for Empirical's goals and ambitions.



STUDYING CARETAKER'S POTENTIAL

When CareTaker's development was finalized, Empirical began selling the device for investigative use mostly in MRIs, since MRIs currently have no alternatives for beat-by-beat blood-pressure measurement. Empirical now has 25 of these units in seven countries around the world and another 25 units involved in clinical trials designed to study the early detection of preeclampsia, the replacement of arterial catheters, spinal–tap anesthesia monitoring for difficult births among the morbidly obese, and surgical operations.

Empirical was also able to show in a clinical trial that CareTaker tracked central blood pressure as opposed to peripheral blood pressure. Additionally, the company conducted tests funded by the National Institutes of Health (NIH) to show that CareTaker could be used for continuous monitoring of blood pressure during dialysis, a safety feature necessary for home dialysis.

In a blind study at the University of Virginia Hospital, Empirical detected and located five of five aortic aneurysms all from signals obtained at the wrist.

In a separate, but related use of CareTaker's technologies, Empirical has recently spearheaded a project to detect equine blood pressure and heart rate. Because a horse's pain can only be measured by elevated blood pressure and heart rate, CareTaker has proven to be uniquely useful in this humane and innovative endeavor that has attracted worldwide attention.

EXPANDING RESEARCH AND DEVELOPMENT

In 2010, Empirical won another $1.7 million in funding from the Office of Naval Research via the Office of the Secretary of Defense for improvements and clinical trials related to CareTaker's use. Empirical also began production prototypes of CareTaker and completed clinical trials from 50 blood donors showing the sensitivity of CareTaker's hemorrhage detection. Empirical conducted dehydration studies in Singapore and at the University of Montana, and right now, the company is monitoring 50 patients in ICUs against arterial catheters as part of a study related to obtaining FDA approval for CareTaker.

In 2012, CareTaker will be used at the University of Texas Medical Branch in a study of algorithmic fluid resuscitation that will benefit from beat-by-beat blood pressure. The company plans to build arrhythmia classification and detection into the device. CareTaker can determine atrial fibrillation in as little as 10 heartbeats and should auto-diagnose congestive heart failure, which is the greatest single cause for hospital readmissions.

Late in 2010, the company won $850,000 from the Army to build a rheoencephalography system, now going into clinical trials, for the neuro-monitoring of traumatic brain injury from explosive blasts. Clinical trials will also assess this system for detection of dangerous vasospasms due to accidents or surgery.

"These systems required a small, inexpensive beat-by-beat blood-pressure monitor, and CareTaker filled that bill," Gerdt said. "It is the first rheoencephalography system that is totally noninvasive."

A FIELD OF UNLIMITED POSSIBILITIES

Over 10 years ago, Gerdt and his two Empirical colleagues received a solicitation from the Defense Advanced Research Projects Agency (DARPA) to find a remote method to determine whether soldiers or marines in combat areas were dead or alive before a medic or corpsman was sent in on a rescue mission.

"Twenty-five percent of warfighters who are killed are going after other warfighters who have already died," Gerdt said.

Once Empirical began the study of remote vital signs, Gerdt and his team found that there was more and more to be done with remote detection, and from there, the company's technology grew into personal healthcare needs at home, far from the battlefield.

Once CareTaker is FDA-approved for the wider market, Gerdt foresees the device having an immense impact on healthcare.

"I think the biggest impact we'll have is for diagnosing illnesses at home and keeping people out of the hospitals," Gerdt said.

The goal is to introduce a multi-parameter vital-signs system that will be inexpensive and can sit in the bathroom closet next to the thermometer, all with cellular radio connection to a Cloud server.

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"The more parameters you can get out of one instrument," Gerdt explained, "the better chance you have to diagnose different medical problems. A lot of monitors these days just monitor one thing, and that's never good enough for remote diagnosis."

CareTaker, however, can be worn while a person is sleeping and shows the user every time they have an apnea arousal. Software analysis counts the arousals and detects their severity by measuring the continuous blood-pressure changes due to these events.

REPLACING ARTERIAL CATHETERS

Starting in 2012, Empirical's ultimate goal is to replace most arterial catheters altogether. Gerdt said that the cost of the mechanical parts in an arterial catheter, plus the cost of the surgeon, is more than the cost of their unit. About one percent of arterial catheters cause blood-borne infections or clots. Infections can cost from $30,000 to $65,000 to cure, and blood clots are similar with both resulting in more time in the hospital, more drugs, more pain, and excessive danger to the patient.

"Most arterial catheters are simply not necessary with a noninvasive device," he said, "and CareTaker presents a way to perform the same functions."

CareTaker is also small and light and able to sit on the back of a wrist. It has a battery charge that lasts for 24 hours and can now stream data continuously to an Android phone, which continuously sends that data to a Cloud server.

"We see it as a device that would bring a lot of medical diagnosis into the home," Gerdt said. With the physician or nurse, it could be used to remotely adjust or modify drug dosages and it could be used to treat patients remotely, especially in rural areas."

BY PETE FERNBAUGH